

Attorney Docket No. I-6909-1919 US

REMARKS

Upon entry of the above amendment, claims 35-41 and 45-59 will be pending in the present application. Claims 1-34 have been previously cancelled. Applicants have canceled claims 42-44. New claims 51-58 are supported by claim 36, 40 and their dependent claims. Applicants have amended the pending claims to clarify the subject matter claimed, to correct syntax and to correct typographical errors. Applicants have not raised any issues of new matter.

Objection to the Specification

The specifications stands objected to for the use of various trademarks without generic terminology. Applicants respectfully traverse this objection.

A previous response addressed this issue by capitalizing every trademark and indicating terms as being trademarks. The Examiner has acknowledged that the trademarks are properly capitalized, but the Examiner asserts generic terminology is required.

The MPEP §608.01(v) states that "if the product to which the trademark refers to is set forth in language that its identity is clear, the examiner are authorized to permit the use

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of the trademark if it is distinguished from common descriptive nouns by capitalization. If it has a fixed and definite meaning, it constitutes sufficient identification unless some physical or chemical characteristic of the article or material is involved in the invention." Applicants again assert that a skilled artisan understands the trademarked products within the context of the specification. The trademarked products are generally research tool such a silica gel and electrophoresis gel, etc. The addition of generic terminology to the specification describing these well known trademarked items is overly burdensome and not required by statute or the rules. More importantly, the trademarked products do not have a physical or chemical characteristic involved in the invention.

If the Examiner determines that a specific Trademark is overly vague, Applicants request the Examiner to identify specifically by page and line. This will provide further clarification as to the terms objected to and the record will be clearer in case of appeal.

Applicants respectfully request withdrawal of the objection to the specification.

#### Claim Objection

Claims 24 and 30 stand objected to. Claim 30 is objected to because *Dictyocaulus viviparus* is misspelled. Applicants

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have canceled claim 30, but have corrected the typographical error in new claim 46.

Applicants have canceled claim 24 and corrected any syntax problems in the new claims.

Applicants respectfully request withdrawal of the objections to claims 24 and 30.

Issue Under 35 U.S.C. §112, First Paragraph

Claim 23 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter outside the scope of enablement. The Examiner asserts that the specification is not enabling for "parts thereof" of SEQ ID NO: 29.

New claim 41 recites an isolated nucleic acid comprising SEQ ID NO: 29 or a nucleic acid that hybridizes to SEQ ID NO: 29 under stringent conditions of 6X SSC at 68 °C. Applicants define the term "stringent conditions" on page 7, in the third paragraph. The defined stringent hybridization conditions of 6 x SSC, 68 °C requires that the fragments be of considerable length and homology to hybridize to the described sequences.

A skilled artisan would not understand the limitations as meaning "a nucleic acid consisting of as few as two

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nucleotides", as suggested by the Examiner. In section 2422.01 of MPEP 8, this shows:

2422.01 Definitions of Nucleotide and/or Amino Acids for Purpose of Sequence Rules:

"Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides."

". . . the limit of ten or more nucleotides, while lower than certain industry database limits, was established to encompass those nucleotide sequences to which the smallest probe will bind in a stable manner."

(emphasis added).

This means the USPTO itself considers nucleotide sequences of less than 10 nucleotides unfit for stable binding to a probe, very much in agreement with the practical situation. Therefore, the referral in claim 23 to a nucleic acid hybridizing to Seq. Id. no. 29 would **not** comprise nucleotides smaller than 10 bases, based on the USPTO's understanding of the size of the match required for stable hybridizations.

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Claim 23 (New claim 46) as interpreted by the definitions found in the specification, clearly is understandable and enabled. "Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." MPEP §2173.05(b).

A skilled artisan would fully understand how to produce an isolated nucleic acid that hybridizes to SEQ ID NO: 29 under stringent conditions, as defined.

Applicants respectfully request withdrawal of the 35 U.S.C. §112, first paragraph rejection.

Issue Under 35 U.S.C. §112, First Paragraph

Claims 24-25 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter outside the scope of enablement. The Examiner asserts that the specification is not enabling for "parts thereof" of the listed SEQ ID numbers.

Applicants have canceled claims 24 and 25 in a previous amendment and have not added a similar claim the application.

Applicants respectfully request withdrawal of the 35 U.S.C. §112, first paragraph rejection.

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Issues Under 35 U.S.C. §112, Second Paragraph

Claims 24-26 stand rejected under 35 U.S.C. §112, second paragraph, for being indefinite. Applicants traverse this rejection.

Applicants have canceled claims 24, 25 and 26 in a previous amendment and have not added a similar claim the application.

Applicants respectfully request withdrawal of the 35 U.S.C. §112, first paragraph rejection.

Issue Under 35 U.S.C. §102(b)/103(a)

Claims 17-20 and 29-31 stand rejected under 35 U.S.C. §102(b) for anticipation or, alternatively, under 35 U.S.C. §103(a) for being obvious over de Leeuw et al (Veterinary Parasitology Vol. 39 No. 1-2, 1991, pages 137-147, IDS-10). Claims 17-20 and 29-31 stand rejected under 35 U.S.C. §102(b) for anticipation or, alternatively, under 35 U.S.C. §103(a) for being obvious over Schneider (International Journal of Parasitology, Vol. 22, No. 7, 1992, pages 933-938). Applicants respectfully submit that patentable distinctions exist between the cited prior art and the present invention.

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Distinctions Between the Present Invention and de Leeuw et al.  
and Schneider

Schneider discloses an amino acid sequence of the Dv3-14 protein, which is available as entry AAB27962, from the NCBI protein database. Using standard sequence alignment software, a homology of around 17% is revealed between Dv3-14 and Dv 17, which is SEQ ID No. 30 of the present application. Therefore, a skilled artisan would not find Dv 17 and Dv3-14 related in any manner.

de Leeuw et al. disclose an immunogenic protein of *Dictyocaulus viviparus* with a molecular weight of 17,000 daltons. The Examiner maintains that Applicants' claim limitations reasonably appear to be the identification of new features of a protein already known in the art. The Examiner acknowledged the 37 C.F.R. §1.132 Declaration by Mr. Hoffman, but found the declaration non-persuasive because of lack of factual evidence.

Applicants direct the Examiner to the Amendment filed April 21, 2003 for arguments regarding claims 35-41 and 46-50. From this actual evidence presented in the 37 C.F.R. §1.132 Declaration, Mr. Cornelissen concluded that the 17kd protein of de Leeuw et al. and the 18kd protein of Schneider must be similar proteins and, therefore, must be different from the presently claimed proteins because 18kd protein is different

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from the instant proteins, as stated above. Therefore, as Dv 17 is not related to Dv 3-14, which is similar to the de Leeuw protein? A skilled artisan definitely would not find the present invention described within the cited references. More, importantly a skilled artisan would not find the present invention obvious from reading the cited references because neither reference provides motivation to alter their teachings in any manner.

Applicants would like to emphasize that new claim 51-59 have been added and are directed to specific amino acid sequences and nucleic acid molecules. Applicants assert that the identified prior art fails to disclose or suggest the subject matter of claims 51-59.

Applicants respectfully request withdrawal of the 35 U.S.C. §102(b)/§103(a) rejections over the cited prior art.

### Conclusion

Applicants submit that every issue raised by the outstanding Office Action has been addressed and rebutted. Therefore, the present claims define patentable subject matter and are in condition for allowance.

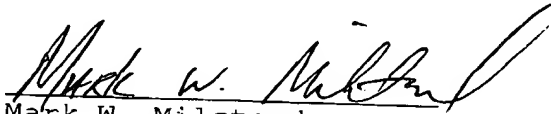
Applicants believe that the conference was helpful in advancing the prosecution of this application.



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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,



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